Establishment of a National Primary Liver Cancer Registry

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on behalf of the Upper Gastrointestinal Cancer Registry Primary Liver Cancer Working Party and Steering Committee, UGICR Liver Module Retrospective Project and Prospective Registry Principal Investigators

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UPPER GASTROINTESTINAL CANCER REGISTRY

Clinical Quality Registries (CQRs) systematically collect, analyse and report clinical data on a whole population basis with a view to monitoring and improving quality (appropriateness and effectiveness) of health care across health services (ACSQHC, 2014).

The Upper Gastrointestinal Cancer Registry (UGICR) is a multi-modular CQR, examining quality of care and outcomes of patients with newly diagnosed primary upper gastrointestinal cancers **(Fig. 1).**

The primary liver module will include sites from Western Australia (WA), South Australia (SA) and Queensland (QLD), Northern Territory (NT) in addition to sites in New South Wales (NSW) and Victoria (VIC). The liver module has received widespread engagement across the different states and territories.

The registry's minimum data sets cover much of the patient pathway from diagnosis to death using clinical data sourced primarily from manual record review. The UGICR piloted the collection of Patient-Reported Outcome Measures (PROMs) for the Pancreatic Module and will do so as well for the Primary Liver Cancer Module in the future.

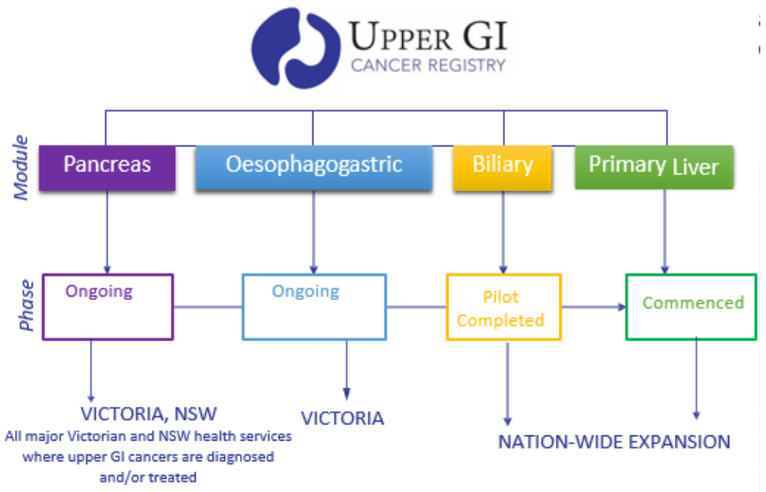

Figure 1. The UGICR: a multi-modular clinical quality registry with a staged roll-out approach

GOVERNANCE

The UGICR Steering Committee oversees all registry activities and guides strategic direction of the registry. The Primary Liver Working Party provides specific guidance on the primary liver cancer module and consists of a range of specialists involved in the care of patients with primary liver cancer including surgeons, medical oncologists, radiation oncologists, and palliative care physicians from various health services, as well as consumers.

The UGICR Primary Liver Module Management Committee is responsible for the day-to-day operation of the study, developing study materials and documentation, database management, and reporting. Regular meetings are held to ensure operations and milestones of the study were met.

EXPANSION OF THE PRIMARY LIVER CANCER MODULE AIMS

- To establish a prospective, population-based hepatocellular carcinoma (HCC) clinical registry across Australia
- To improve the quality of care provided to patients with HCC

OPTIMAL CARE PATHWAY

The optimal care pathway for patients with HCC formed the basis of the Delphi with the aim to determine what is evidence-based best practice that determines optimal care ***(Fig. 2)***.

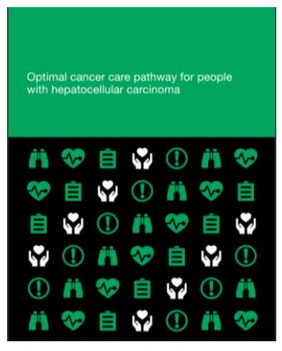

Figure 2. Optimal cancer care pathway for people with HCC

METHODS

Figure 3 illustrates the three key phases of CQR development and operation.

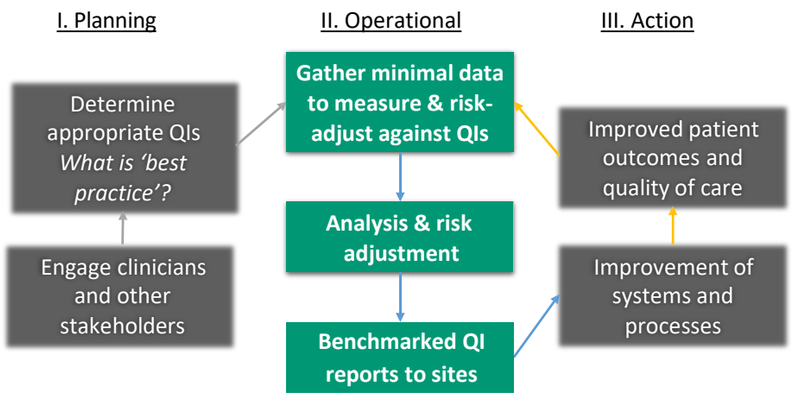

Figure 3. CQR processes - simplified

PHASE 1: CLINICAL QUALITY INDICATORS DEVELOPMENT DELPHI

A Modified Delphi (mDelphi) of clinical experts from different fields and consumers reviewed current guidelines and developed a set of 23 quality indicators (QIs) which reflect performance against agreed 'best-practice' in primary liver cancer care ***(Table 1)***.

Ashika D. Maharaj, et. al. (2022). Monitoring quality of care in hepatocellular carcinoma: A modified Delphi consensus. Journal of Hepatology Communications. http://doi.org/10.1002/hep4.2089

Table 1: Final consensus quality indicator set

1	Specialist investigations to achieve a diagnosis completed within 4 weeks of referral
2	Documented evaluation at baseline of underlying liver disease aetiology, presence/absence of cirrhosis, alfa-fetoprotein (AFP) level, extent of liver dysfunction (e.g. Child-Pugh Score or MELD and presence or absence of portal hypertension) and comorbidities (that impact on management)
3	Documented regular surveillance with ultrasound and/or appropriate alternative liver imaging performed within 6-12 months before the first detection of HCC in known cirrhotic and at-risk patients managed though a specialist centre
4	Diagnosis of HCC is confirmed either by established imaging criteria (e.g. Liver Imaging and Reporting Data System [LI-RADS] using multiphase CT or MRI or CEUS) or histologically
5	Documented diagnosis in non-cirrhotic patients (not known to be at increased risk of HCC) is confirmed by histopathology
6	Tumour stage is clearly defined and documented using the BCLC staging system (Stage 0, Stage A- D)
7	All cirrhotic patients are stratified according to Child-Pugh score and / or MELD and BCLC staging system
8	Documented staging parameters include radiological imaging (tumour size, number and location of lesions, metastases and vascular invasion), Eastern Cooperative Oncology Group (ECOG) performance status and cirrhosis status and assessment of liver function (e.g. Child–Pugh score or MELD)
9	Diagnosis, staging and treatment planning of a patient with suspected or proven HCC is managed by a multidisciplinary team (MDT)
10	Patients with HCC (with or without cirrhosis) and viral hepatitis B or C should receive antiviral therapy
11	Patients with early stage HCC should receive therapy with curative intent
12	Liver resection offered as first line therapy in patients with preserved liver function, sufficient liver remnant, and absence of significant portal hypertension (or a valid reason for not undergoing treatment)
13	Documented discussion of liver transplantation in patients within overall transplant criteria who are not suitable for curative hepatic resection or ablative therapy
14	Patients with HCC on the waiting list for liver transplantation should be monitored for HCC progression.
15	TACE or TARE or other therapy with intent to delay progression and prolong survival is offered to patients with BCLC-B HCC not suitable for curative treatment
16	Documented response to HCC-directed treatment with contrast-enhanced CT or MRI every 3-6 months
17	Documented that systemic therapy was offered to suitable patients with advanced HCC not amenable to curative or locoregional therapies with intent to prolong survival
18	Currently approved first-line systemic therapy was offered to eligible patients with HCC
19	Patients with BCLC-D are offered symptom management in conjunction with supportive care services
20	Patients referred to palliative care in advanced disease
21	Clinical and radiological (multiphase CT or MRI using standardised criteria) assessment completed to monitor treatment response
22	Treatment commences within 4 weeks of decision to treat (from MDT)
23	Post-operative 90-day mortality after liver resection in patients with cirrhosis should be less than 3%

PHASE 2: DATA MAPPING, MINIMUM DATASET & DATABASE DEVELOPMENT

All HCC-related fields from majority of the participating primary liver cancer module sites were mapped against the registry database and each other. Similarities in field name, format and options were looked at. There was very limited similarity among site unit databases, which highlighted the need for a standardised national database.

The UGICR Primary Liver Module minimum dataset (MDS) was developed following the mDelphi. The MDS was developed carefully to ensure data items needed to report on QIs were included: demographics/notifying hospital information; vital status; diagnosis; treatment; other care and treatment; end of life details.

The MDS informed the creation of the primary liver cancer module database. Patients are assessed by site data collectors for eligibility ***(Fig 4)***.

PHASE 3: DATA COLLECTION (ONGOING)

There are currently eight sites in VIC and two in NSW actively collecting data.

Currently, there is a total of 321 participants in the screening database and 268 of those participants have been recruited into the UGICR Liver module. There have been thirteen training sessions completed.

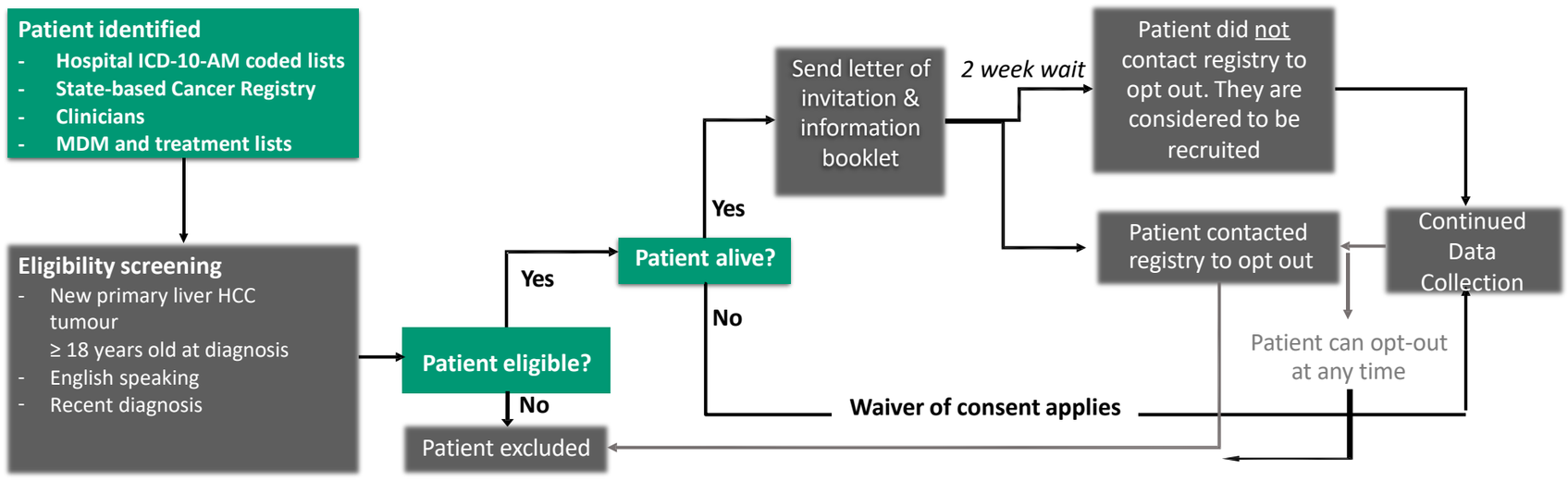

Figure 4. Recruitment processes for the Upper Gastrointestinal Cancer Registry